

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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NMT Medical, Inc.,

Plaintiff,

v.

Civil Action # 04-12565 NG

AGA Medical Corporation

Defendant.

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**DEFENDANT AGA MEDICAL CORP.'S  
ANSWER AND COUNTERCLAIM**

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AGA Medical Corp., Defendant in the above-captioned case, in response to Plaintiff's Complaint for infringement of United States Patent No. 5,108,420 denies each and every allegation contained therein unless expressly admitted below.

1. In response to Paragraph 1 of the Complaint, Defendant admits that Plaintiff NMT Medical, Inc. has a principal place of business in Boston, Massachusetts. Defendant lacks sufficient information regarding Plaintiff's corporate status and state of incorporation and therefore denies the same.
2. In response to Paragraph 2 of the Complaint, Defendant admits that is a corporation organized and existing under the laws of the state of Minnesota, having its principal place of business in Golden Valley, Minnesota.
3. In response to Paragraph 3 of the Complaint, Defendant admits that Plaintiff alleges an action for patent infringement arising under Title 35 of the United States Code, but denies that any infringement has occurred.
4. Defendant denies each and every allegation of Paragraph 4 of the Complaint. .

5. Defendant lacks sufficient information concerning Plaintiff's rights under U. S. Patent 5,108,402 (the '420 patent) to form a belief and therefore denies each and every allegation of Paragraph 5.

6. Defendant admits the allegations of Paragraph 6.

7. In response to Paragraph 7 of the Complaint, Defendant admits that during the course of the parties' prior litigation, it became clear that at least two pieces of prior art were not before the Patent and Trademark Office ("PTO") when the '420 patent was originally prosecuted.

8. In response to Paragraph 8, the Defendant admits that on April 25, 2001, the Court granted NMT's motion to stay the proceedings in the parties' original litigation pending reexamination of the '420 patent by the PTO.

9. In response to paragraph 9, the Defendant admits that on June 25, 2001, the inventor of the '420 patent submitted the '420 patent to the PTO for reexamination on light of the purported art.

10. In response to paragraph 10, the Defendant admits that on October 31, 2002, the Court indicated it would consider dismissing the parties' original litigation without prejudice.

11. In response to paragraph 11 of the Complaint, the Defendant admits that the PTO examiner conducting the reexamination rejected all of the claims of the '420 patent, and denies the remaining allegations of paragraph 11.

12. In response to paragraph 12, Defendant admits that on September 30, 2003, AGA requested the Court dismiss the original litigation without prejudice.

13. In response to paragraph 13, Defendant admits that on December 2, 2003, the Court dismissed the parties' original litigation without prejudice. Defendant denies the remaining allegations of Paragraph 13 of the Complaint.

14. In response to Paragraph 14, Defendant denies each and ever allegation contained therein.

15. In response to Paragraph 15, Defendant admits that AGA brought a complaint in the U.S. District Court for the District of Minnesota for declaratory judgment regarding the issues of non-infringement and invalidity of the '420 patent against NMT and Dr. Lloyd Marks.

16. In response to Paragraph 16 of the Complaint, Defendant restates its responses to Paragraphs 1-15 of the Complaint.

17. Defendant denies each and every allegation contained in Paragraphs 17 and 18 of the Complaint.

#### **AFFIRMATIVE DEFENSES**

18. Defendant further avers, upon information and belief, that the '420 patent is invalid, unenforceable, and void given the statutory requirements of 35 U.S.C. §§ 102, 103, and 112 for one or more of the following reasons:

- (a) The patentee did not invent the subject matter patented, nor did he make any invention or discovery, either novel, original, or otherwise, within the meaning of United States Code, Title 35;
- (b) The alleged invention was made by another in this country before the patentee's alleged invention, and such other person had not abandoned, suppressed, or concealed it;

- (c) The patent does not particularly point out and distinctly claim the part, improvement, method, steps, or combination that the patentee claims as his invention, as required by Title 35, United States Code;
- (d) The specification does not contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most nearly connected, to make, construct, compound, and/or use the same, and the description does not adequately explain the principle or the best mode in which the patentee contemplated applying that principle so as to distinguish it from other inventions, as required by Title 35, United States Code;
- (e) The claims, and each of them, of the patent are excessively vague and indefinite and do not distinctly point out and define the invention;
- (f) The claims, and each of them, are not directed to patentable combinations, but are directed to mere aggregations of parts or steps, means, or elements which were matters of common knowledge in the art to which said patent relates before the alleged invention and more than one year prior to the date of the application for the patent;
- (g) In light of the prior art at the time the alleged invention was made, the subject matter as claimed in the patent would have been obvious to one skilled in the art to which the alleged invention relates and does not constitute patentable invention;
- (h) The alleged invention or discovery was disclosed in a United States patent to another, the application for which was filed before the alleged invention by the patentee of the Patent in Suit;

(i) More than one year prior to the filing of the original application which matured into the Patent in Suit, the alleged invention was patented or described in printed publications in this or in foreign countries, or was in public use or on sale in this country;

(j) Before the alleged invention or discovery by the patentee, the alleged invention was known or used by others than the alleged inventor and was on sale in this country and was patented or described in printed publications in this or in foreign countries;

(k) The patent owner added new matter to the patent during the reexamination proceeding.

19. Defendant further avers that any claims of the '420 patent which may be held to be valid are so restricted in scope that Defendant has not infringed said claims.

20. Defendant avers that amendments to the claims and arguments presented to the patent examiner during prosecution of the '420 patent restrict the scope of the claims and constitute Prosecution History Estoppel barring a finding of infringement.

21. Defendant has not done any act or thing and is not proposing to do any act or thing in violation of any rights validly belonging to Plaintiff under any patent owned by Plaintiff. The '420 patent is invalid and unenforceable, is not infringed by Defendant, and Defendant is not liable for infringement of said patent.

22. Plaintiff has failed to name Dr. Lloyd A. Marks, the purported owner of the '420 patent, as a party. Dr. Marks is a person needed for a just adjudication.

### **COUNTERCLAIMS**

23. This Court has jurisdiction over AGA's federal claims by virtue of the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 and the laws of the United States concerning actions relating to patents. This Court has personal jurisdiction over NMT

**COUNTERCLAIM COUNT I --  
INVALIDITY AND NON-INFRINGEMENT OF PATENT**

24. AGA restates Paragraphs 1-23 of this Complaint.
25. Lloyd A. Marks claims to be the owner of U.S. Patent No. 5,108,420 issued on April 28, 1992 (the “‘420 Patent”). NMT claims to own an exclusive license under the ‘420 patent.
26. As a result of the acts set forth below, an actual justiciable controversy exists between Defendants and AGA with respect to the validity of the ‘420 Patent and Defendants' claims that AGA's products infringe the ‘420 Patent.
27. On December 10, 1998, Defendants commenced litigation in the U.S. District Court for the District of Massachusetts against AGA for infringement of the ‘420 Patent (hereinafter referred to as “the Massachusetts Litigation”).
28. On April 25, 2001, the District Court stayed the Massachusetts Litigation pending a reexamination of the ‘420 patent by the United States Patent and Trademark Office. On December 1, 2003, the District Court of Massachusetts dismissed the litigation without prejudice.
29. During the reexamination of the ‘420 Patent, the Patent Office Examiner rejected the claims. However, on August 19, 2004, the Patent and Trademark Office Board of Appeals purportedly reversed the examiner's rejection.
30. On September 7, 2004, Defendants issued a press release in which John E. Ahern, the President and CEO of NMT declared:

“[t]he Board of Appeals decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively.”

(emphasis added).

31. AGA's position has consistently been that it has not infringed the '420 Patent and that the '420 Patent is invalid and unenforceable.

32. By virtue of the exchanges outlined above, there is a substantial and continuing justiciable controversy between AGA and Defendants as to Defendants' rights in the '420 Patent, the validity and enforceability of the '420 Patent, and as to AGA's continuing right to make, use and sell its products.

33. AGA contends that the claims for the '420 Patent, including any claims which may have survived reexamination, are not infringed by AGA.

34. In the alternative, AGA contends that the claims for the '420 Patent, including any claims which may have survived reexamination, are invalid, unenforceable, and void since they have not and may not be duly or legally issued for many reasons including, without limitation, that each are invalid, unenforceable, and void given the statutory requirements of 35 U.S.C. §§ 102, 103 or 112 for one or more of the following reasons:

a. The patentee did not invent the subject matter patented, nor did he make any invention or discovery, either novel, original, or otherwise, within the meaning of United States Code, Title 35;

b. The alleged invention was made by another in this country before the patentee's alleged invention, and such other person had not abandoned, suppressed, or concealed it;

- c. The patent does not particularly point out and distinctly claim the part, improvement, method, steps, or combination that the patentee claims as his invention, as required by Title 35, United States Code;
  
- d. The specification does not contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it most nearly connected, to make, construct, compound and/or use the same, and the description does not adequately explain the principle or the best mode in which the patentee contemplated applying the principle so as to distinguish it from other inventions, as required by Title 35, United States Code;
  
- e. The claims, and each of them, of the patent are excessively vague and indefinite and do not distinctly point out and define the invention;
  
- f. The claims, and each of them, are not directed to patentable combinations, but are directed to mere aggregations of parts or steps, means, or elements which were matters of common knowledge in the art to which said patent relates before the alleged invention and more than one year prior to the date of the application for the patent;

g. In light of the prior art at the time the alleged invention was made, the subject matter as claimed in the patent would have been obvious to one skilled in the art to which the alleged invention relates and does not constitute patentable invention;

h. The alleged invention or discovery was disclosed in a U.S. patent to another, the application for which was filed before the alleged invention by the patentee of the Patents-in-Suit;

i. More than one year prior to the filing of the original application which matured into the Patents-in-Suit, the alleged invention was patented or described in printed publications in this or in foreign countries, or was in public use, or on sale in this country;

j. Before the alleged invention or discovery of the patentee, the alleged invention was known or used by others than the alleged inventor and was on sale in this country and was patented or described in a printed publication in this or in foreign countries;

k. The patent owner added new matter to the patent during the reexamination proceeding..

35. AGA further avers that any claims of the ‘420 Patent, including any claims which may have survived reexamination, which may be held to be valid are so restricted in scope that AGA has not infringed said claims.

36. As a result of the proceedings in the U.S. Patent and Trademark Office during the prosecution of the applications and reexamination proceedings for the '420 Patent and the admissions and representations made in the proceedings by or on behalf of the applicant, Defendants are estopped under the doctrine of prosecution history estoppel and may not now seek or maintain a construction for the claims of the '420 Patent, were the same otherwise possible, to cover or embrace any products made, used, or sold by AGA.

37. The Patent Statutes provide, in part, that during a reexamination proceeding in the Patent and Trademark Office “[n]o proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding...” 35 U.S.C. § 305 (2003). Because none of the original claims of the '420 patent cover AGA's products or conduct AGA cannot be found to infringe any claim added or amended during reexamination.

38. AGA has not done any act or thing and is not proposing to do any act or thing in violation of any rights validly belonging to Defendants under any patent owned by Defendants. The '420 Patent is invalid and unenforceable, and not infringed by AGA, and AGA is not liable for infringement of said patents.

#### PRAYER

WHEREFORE, AGA prays that:

1. Entry of judgment providing:
  - a. A declaration that Defendants is without right or authority to threaten or maintain suit against AGA for alleged infringement of the '420 Patent, including any claims which may have survived reexamination.

b. A declaration that the claims of '420 Patent, including any claims which may have survived reexamination, are invalid, unenforceable and void in law.

c. A declaration that the claims of '420 Patent, including any claims which may have survived reexamination, are not infringed by AGA.

d. AGA be awarded its costs and attorneys fees related to this suit.

e. Preliminary and permanent injunctive relief enjoining Defendants, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with it who receive actual notice of the injunction from initiating infringement litigation or threatening AGA or any of its customers, dealers, agents, servants, or employees, or any perspective or present sellers, dealers, or users of AGA's products, with infringement litigation, or charging any of them verbally or in writing with infringement of the '420 Patent because of the manufacture, use, sale, or offering for sale of the AGA's products.

2. All other relief that the Court may deem appropriate.

Respectfully submitted,

Dated: March 9, 2005

/s/ James T. Nikolai  
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